K082258

OCT 1 6 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Contact Person:

Mr. Gary Steinberg
President
Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Date Summary Prepared: July 1, 2008

2. **Name of Device:**

- Crosstex® Isolite® Earloop Face Masks – Blue, Pink
- Crosstex® Isofluid® Earloop Face Masks – Blue, Pink, White, Green
- Crosstex® Isofluid FogFree® Earloop Face Masks – Blue, Peach
- Crosstex® Isofluid FogFree® Face Masks with Splash Visor – Blue, Peach
- Crosstex® Procedural Earloop Face Masks – Blue, Pink, Yellow
- Crosstex® Ultra Fluid Resistant No-Fog® Earloop Face Masks – Blue
- Crosstex® Ultra Fluid Resistant No-Fog® Face Masks with Splash Visor – Blue

3. **Predicate Device Information:**

a. American Threshold Industries, Surgical Masks, K# 801036, Asheville, North Carolina.
b. American Threshold Industries, Fluid Resistant Masks, K# 955556, Enka, North Carolina.

4. **Device Description:**

The seven (7) Crosstex® Surgical Masks are constructed of either an inner/outer facing of tissue or 100% spunbonded polypropylene, a 100% meltblown polypropylene filter media, with white elastic loops and/or a fogfree strip. The nose piece for all seven (7) Crosstex® Surgical Masks is 27 gauge aluminum wire, some have an anti-fog strip, with the Crosstex® Ultra Fluid Resistant No Fog® having a vapor barrier. All of the materials used in the construction of the Crosstex® Surgical Masks are being used in currently marketed devices (see predicate information).

5. **Intended Use:**

The following Crosstex® Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

- Crosstex® Isolite® Earloop Face Masks – Blue, Pink
- Crosstex® Isofluid® Earloop Face Masks – Blue, Pink, White, Green
- Crosstex® Isofluid FogFree® Earloop Face Masks – Blue, Peach
- Crosstex® Isofluid FogFree® Face Masks with Splash Visor – Blue, Peach
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6. **Comparison to Predicate Devices:**

See Attached

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

a. Fluid Resistance:
   - Liquid (Water) Resistance Test/Impact Penetration Test
b. Bacterial Filtration Efficiency (BFE) / Differential Pressure ($\triangle$P) Tests
c. Flammability Testing
d. Latex Particle Challenge Test
e. Biocompatibility Testing Per ISO 10993

It was our conclusion that Performance Testing met all relevant requirements of the aforementioned test standards.

8. **Discussion of Clinical Test Performed:**

Not Applicable

9. **Conclusions:**

The Crosstex® Surgical Masks have the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do no raise any new questions of safety or effectiveness. The Crosstex® Surgical Masks are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Crosstex International, Incorporated
Mr. Richard M. Ormsbee
Senior Regulatory Affairs Specialist
Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447-4822

Re: K082258
Trade/Device Name: Crosstex® Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: September 17, 2008
Received: September 18, 2008

Dear Mr. Ormsbee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082258

Device Name: Crosstex® Surgical Masks

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A Murphy MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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